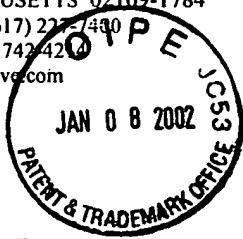


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2176

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Washington, D.C. 20231

December 17, 2001

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JAN 11 2002  
Technology Center 2100

Re: U.S. Patent Application No.: 09/825,534  
*APPARATUS AND METHOD FOR PREDICTION AND MANAGEMENT OF SUBJECT COMPLIANCE IN CLINICAL RESEARCH*  
Inventors: Saul Shiffman et al.  
Filed: April 2, 2001  
Our Ref. No.: IVQ-001

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form 1449;
3. Copies of references cited in PTO Form 1449; and
4. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on:

December 17, 2001

Date

David J. Rikkers, Reg. No. 43,882

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

David J. Rikkers  
Registration No. 43,882  
Attorney for Applicants

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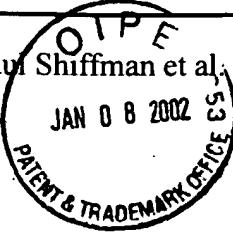
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE *JAN 11 2002*

*Technology Center 2100*

In re the application of: Saul Shiffman et al.

Serial No.: 09/825,534

Filed: April 2, 2001



Group Art Unit: 2176

Examiner: Not yet assigned

For: *APPARATUS AND METHOD FOR  
PREDICTION AND MANAGEMENT OF SUBJECT  
COMPLIANCE IN CLINICAL RESEARCH*

Attorney Docket No.: IVQ-001

Commissioner for Patents  
Washington, D.C. 20231

**Certificate of First Class Mailing (37 CFR §1.8(a))**

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Date of Signature and of Mail Deposit

By:

  
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David J. Rikkers  
Registration No. 43,882  
Attorney for Applicants

**INFORMATION DISCLOSURE STATEMENT**

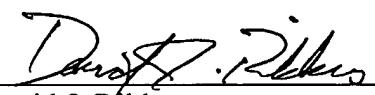
Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

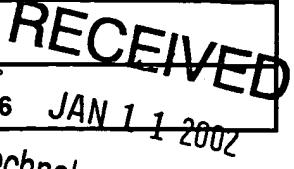
Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

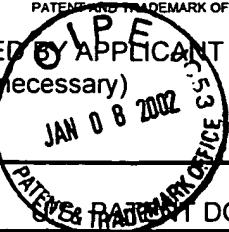
  
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KJC/DJR/ham  
Enclosures

APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-80		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO <b>IVQ-001</b>	SERIAL NO. <b>09/825,534</b>
<b>LIST OF PUBLICATIONS CITED BY APPLICANT</b> (Use several sheets if necessary)		APPLICANT <b>Saul Schiffman et al.</b>	FILING DATE <b>April 2, 2001</b>	GROUP <b>2176 JAN 11 2002</b>
		 <b>Technology Center 2100</b>		



PATENT &amp; TRADEMARK DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	Des. 247,251	02/78	Napoli	D24	17	
	A2	4,262,632	04/81	Hanton et al.	119	1	
	A3	4,353,375	10/82	Colburn et al.	128	782	
	A4	4,367,752	01/83	Jimenez et al.	128	689	
	A5	4,543,955	10/85	Schroeppele	128	635	
	A6	4,566,461	01/86	Lubell et al.	128	668	
	A7	4,592,018	05/86	Wiegman	365	63	
	A8	4,686,624	08/87	Blum et al.	364	415	
	A9	4,803,625	02/89	Fu et al.	364	413.03	
	A10	4,844,076	07/89	Lesho et al.	128	631	
	A11	4,883,063	11/89	Bernard et al.	128	670	
	A12	4,909,260	03/90	Salem et al.	128	721	
	A13	4,966,154	10/90	Cooper et al.	128	671	
	A14	4,974,601	12/90	Tranjan et al.	128	696	
	A15	4,975,842	12/90	Darrow et al.	364	413.02	
	A16	4,987,897	01/91	Funke	128	419 PG	
	A17	5,002,064	03/91	Allain et al.	128	710	
	A18	5,063,937	11/91	Ezenwa et al.	128	723	
	A19	5,078,134	01/92	Heilman et al.	128	421	
	A20	5,111,818	05/92	Suzuki et al.	128	644	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES      NO
	A21	WO 88/02237 A1	04/88	PCT			
	A22	EP 299667 A1	01/89	EPO			
	A23	WO 89/05116 A1	06/89	PCT			
	A24	FR 2686497 A1	07/93	France			Abstr.
	A25	WO 94/01040 A1	01/94	PCT			
	A26	WO 94/13198 A1	06/94	PCT			
	A27	WO 94/24929 A1	11/94	PCT			

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A28	Bradburn, NM, et al. "Answering Autobiographical Questions: The Impact of Memory and Inference on Surveys" <i>Science</i> 10 Apr 1987;236:157-161		
Examiner	Date Considered		
EXAMINER:	Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-80		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO <b>IVQ-001</b>	SERIAL NO. <b>09/825,534</b>
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		<b>GROUP</b> <b>2176</b>		

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B1	5,113,859	05/92	Funke	128	419 PG	JAN 11 2002 Technology Center 2100
B2	5,128,552	07/92	Fang et al.	307	66	
B3	5,131,390	07/92	Sakaguchi et al.	128	632	
B4	5,137,345	08/92	Waldorf et al.	351	206	
B5	5,181,519	01/93	Bible	128	704	
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B27	Collins, RL, et al. "Ecological momentary assessment in a behavioral drinking moderation training program" <i>Exp. Clin. Psychopharmacol.</i> 1998 Aug;6(3):306-315
B28	Cramer, JA, et al. "How often is medication taken as prescribed?" <i>JAMA</i> 1989 Jun 9;261(22):3273-3277
B29	Eich, E, et al. "Memory for Pain: Relation between Past and Present Pain Intensity" <i>Pain</i> 1985;23:375-380
B30	Friedman, WJ "Memory for the Time of Past Events" <i>Psychological Bulletin</i> 1993;113(1):44-66

Examiner	Date Considered
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APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-60		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO <b>IVQ-001</b>	SERIAL NO. <b>09/825,534</b>
LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)		RECEIVED JAN 11 2001 Technology Center 2100		
		APPLICANT <b>Saul Shiffman et al.</b>	FILING DATE <b>April 2, 2001</b>	GROUP <b>2176</b>
<i>JAN 08 2002 C53</i> OTHERS (including Patent Number, Date, Pertinent Pages, Etc.)				

C1	Gorin, AA, et al. "Recall Biases and Cognitive Errors in Retrospective Self-Reports: A Call for Momentary Assessments" <i>Handbook of Health Psychology</i> . Lawrence Erlbaum Assoc.:Mahwah, New Jersey. 2001;pp. 405-413
C2	Greeno, CG, et al. "Binge antecedents in obese women with and without binge eating disorder" <i>J. Consult. Clin. Psychol.</i> 2000 Feb;68(1):95-102
C3	Hyland, ME, et al. "Diary keeping in asthma: comparison of written and electronic methods" <i>BMJ</i> 20 Feb 1993;306(6876):487-489
C4	Kamarck, TW, et al. "The effects of psychosocial influences on ambulatory blood pressure: contrasting different measurement and data analytic strategies" 37 <sup>th</sup> Annual Meeting of the Society for Psychophysical Research, N. Falmouth, Massachusetts, USA, Oct. 15-19, 1997. <i>Psychophysiology</i> 1997;34 (Suppl. 1):S6-S7
C5	Kamarck, TW, et al. "Effects of task strain, social conflict, and emotional activation on ambulatory cardiovascular activity: daily life consequences of recurring stress in a multiethnic adult sample" <i>Health Psychol.</i> 1998 Jan;17(1):17-29
C6	Kamarck, TW, et al. "Emotional Support Modulates The Acute Pressor Effects Of Stress During Daily Life" Abstracts of Papers for 1999 Annual Meeting: Paper Session: Cardiovascular Activity in Relation to Stress Psychology and Neurobiology. <i>Psychosomatic Medicine</i> 1999;61(1):112 (abstract)
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C8	O'Connell, KA, et al. "Overcoming the Urge to Smoke: The Strategies of Long-Term Abstainers and Late Relapsers" <i>Psychology of Addictive Behavior</i> 1991;5(1):1-8
C9	O'Connell, KA, et al. "Coping in real time: using Ecological Momentary Assessment techniques to assess coping with the urge to smoke" <i>Res. Nurs. Health.</i> 1998 Dec;21(6):487-497
C10	O'Connell, KA, et al. "Symptom beliefs and actual blood glucose in type II diabetes" <i>Res. Nurs. Health.</i> 1990 Jun;13(3):145-151
C11	O'Connell, KA, et al. "Reversal theory and smoking: a state-based approach to ex-smokers' highly tempting situations" <i>J. Consult. Clin. Psychol.</i> 1990 Aug;58(4):489-494
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C17	Ross, M "Relation of Implicit Theories to the Construction of Personal Histories" <i>Psychological Review</i> 1989;96(2):341-357

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		JAN 11 2002 Technology Center 2100		

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D1	Schwartz, JE, et al. "Does trait coping exist? A momentary assessment approach to the evaluation of traits" <i>J. Pers. Soc. Psychol.</i> 1999 Aug;77(2):360-369
D2	Schwartz, JE, et al. "Strategies for analyzing ecological momentary assessment data" <i>Health Psychol.</i> 1998 Jan;17(1):6-16
D3	Shiffman, S. "Real-Time Self-Report of Momentary States in the Natural Environment: Computerized Ecological Momentary Assessment" <i>The Science of Self-Report: Implications for Research and Practice</i> (A. Stone, et al. eds.) Lawrence Erlbaum Associates:Mahwah, New Jersey. 1989; Chapter 16: 277-296
D4	Shiffman, S. "Assessing Smoking Patterns and Motives" <i>Journal of Consulting and Clinical Psychology</i> 1993;61(5):732-742
D5	Shiffman, S, et al. "Drinking and Smoking: A Field Study of their Association" <i>Annals of Behavioral Medicine</i> 1994;16(3):203-209
D6	Shiffman, S, et al. "Nicotine withdrawal in chippers and regular smokers: subjective and cognitive effects" <i>Health Psychol.</i> 1995 Jul;14(4):301-309
D7	Shiffman, S, et al. "First lapses to smoking: within-subjects analysis of real-time reports" <i>J. Consult. Clin. Psychol.</i> 1996 Apr;64(2):366-379
D8	Shiffman, S, et al. "Progression from a smoking lapse to relapse: prediction from abstinence violation effects, nicotine dependence, and lapse characteristics" <i>J. Consult. Clin. Psychol.</i> 1996 Oct;64(5):993-1002
D9	Shiffman, S, et al. "Temptations to smoke after quitting: a comparison of lapsers and maintainers" <i>Health Psychol.</i> 1996 Nov;15(6):455-461
D10	Shiffman, S, et al. "A day at a time: predicting smoking lapse from daily urge" <i>J. Abnorm. Psychol.</i> 1997 Feb;106(1):104-116
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D12	Shiffman, S, et al. "Individual differences in the context of smoking lapse episodes" <i>Addict. Behav.</i> 1997 Nov-Dec;22(6):797-811
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D14	Shiffman, S, et al. "The effect of bupropion on nicotine craving and withdrawal" <i>Psychopharmacology</i> 2000 Jan;148(1):33-40
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D17	Stone, AA, et al. "Ecological Momentary Assessment (EMA) in Behavioral Medicine" <i>Annals of Behavioral Medicine</i> 1994;16(3):199-202
D18	Stone, AA, et al. "A comparison of coping assessed by ecological momentary assessment and retrospective recall" <i>J. Pers. Soc. Psychol.</i> 1998 Jun;74(6):1670-1680
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				JAN 11 2002 Technology Center JC53

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**Examiner**

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